

## REMARKS

### 1. Preliminary Remarks

#### a. Status of the Claims

Claims 1-11 and 13-22 are pending in this application, of which claims 1-11 and 13 are under active consideration. Claims 1-22 are amended. Applicant respectfully request entry of the amendments and remarks made herein into the file history of the application. Upon entry of the amendments, claims 1-11 and 13-22 will be pending, of which claims 1-11 and 13 will be under active consideration.

#### b. Claim Amendments

The claims are amended throughout to replace the phrase “the general formula,” with “the formula.” The claims are also amended throughout to begin with either “A” or “The” as a appropriate. As an example, claim 1 is amended to read “A guanidine compound,” instead of, “Guanidine compound.” Furthermore, the claims are amended throughout to remove extraneous periods.

Claims 1 and 2 are amended to define Z as each optionally substituted C<sub>1-4</sub>-alkylene or C<sub>1-4</sub>-alkyleneoxy. Support for this amendment is found at page 41, final paragraph of the original specification.

Claim 1 is amended to define R<sup>4</sup> and R<sup>5</sup> being a monocyclic saturated heterocycle or a bicyclic saturated or unsaturated heterocycle, when R<sup>4</sup> and R<sup>5</sup> are a 4-7-membered heterocycle of group 7. Support for this amendment is found at original claim 1 and in the original specification at pages 49 and 53. Claim 1 is also amended to correct the typo, “hetatyl” to “hetaryl.”

Claims 8-10 are amended to remove the boxes drawn around the depicted chemical structures in these claims.

Withdrawn claim 16 is amended to depend from claim 1, and withdrawn claim 17 is amended to depend from claim 2, support for which is found in original claims 16 and 17.

Withdrawn claim 21 is amended to correct the typographical error “migrane” to “migraine.”

#### c. Amendments to the Specification

Applicant submits herewith a substitute specification under 37 C.F.R. § 1.125 in order to remove numerous correction markings that were erroneously left in the specification at the time of filing. These corrections were remnants of “track changes” that had been used while editing the document prior to filing. As a result of the markings, some text was left underlined, the left margin

of pages was marked with lines indicating where changes were made, and some bubbles indicating place where text was deleted or reformatted were shown in the right margin. The correction markings have been removed from the substitute specification solely by accepting all of the changes in the earlier-filed document. Accordingly, the substantive contents of the substitute specification and the originally-filed specification are identical. Consequently, **Applicant hereby states that the substitute specification contains no new matter**, as required under 37 C.F.R. § 1.125(b).

**d. Objections to the Specification**

On page 3 of the Office Action, the Examiner objects to the specification because it contains underlining and formatting notes. As discussed above, the substitute specification submitted herewith removes the underlining and formatting notes, thereby obviating this objection.

**2. Patentability Remarks**

**a. 35 U.S.C. § 112, second paragraph**

On pages 4 and 5 of the Office Action, the Examiner rejects claims 1-11 and 13 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner asserts that phrase “the general formula” in claims 1 and 2 renders the claims indefinite. This phrase has been replaced with the phrase “the formula,” throughout the claims, thereby obviating this rejection.

The Examiner also generally rejects the claims for including periods within the claims, and not just at the ends of the claims. The claims are amended throughout to remove these erroneous periods, thereby obviating this rejection.

The Examiner further rejects claim 1 for misspelling, “hetaryl.” This misspelling is corrected in amended claim 1, thereby obviating this rejection.

The Examiner rejects claims 8-10 for having boxes around the formulas for Q and R<sup>4</sup> and R<sup>5</sup>. The boxes are removed in amended claims 8-10, thereby obviating this rejection.

The Examiner also rejects claim 5 for not ending with a period. Amended claim 5 ends with a period, thereby obviating this rejection. Lastly, the Examiner rejects claim 10 for referring to “(7.)” instead of “(6)”. Amended claim 10 now recites “(6)” thereby obviating this rejection. In view of the foregoing amendment and remarks, Applicant submits that the rejection of claims 1-11 and 13 under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

**b. 35 U.S.C. § 102****(1) Registry No. 260443-24-1**

On pages 5 and 6 of the Office Action, the Examiner rejects claims 1, 2, 4, 6, 10, and 11 under 35 U.S.C. § 102(b) as allegedly being anticipated by Registry No. 260443-24-1 (“the “24-1 Compound”). In view of amended claims 1 and 2, Applicant respectfully submits that the rejection is overcome. Specifically, amended claims 1 and 2 define Z as each optionally substituted C<sub>1-4</sub>-alkylene or C<sub>1-4</sub>-alkyleneoxy. In contrast, as characterized by the Examiner, the 24-1 Compound has, at the equivalent to the Z group of instant formula (I), Z=Z1, where a and c are 0, b is 1, and V<sub>Z</sub> is -SO<sub>2</sub>-. The 24-1 Compound discloses no other alternative to this Z group. Accordingly, the 24-1 Compound does not disclose all of the limitations of the instantly claimed compound, and therefore cannot anticipate the instant claims.

**(2) Registry No. 672884-90-1**

On pages 6 and 7 of the Office Action, the Examiner rejects claims 1-3, 6, 7, 10, and 11 under 35 U.S.C. § 102(b) as allegedly being anticipated by Registry No. 672884-90-1 (the “90-1 Compound”). In view of amended claims 1 and 2, Applicant respectfully submits that the rejection is overcome. Specifically, amended claims 1 and 2 define Z as each optionally substituted C<sub>1-4</sub>-alkylene or C<sub>1-4</sub>-alkyleneoxy. In contrast, as characterized by the Examiner, the 90-1 Compound has, at the equivalent to the Z group of instant formula (I), Z=Z1, where a and c are 0, b is 1, and V<sub>Z</sub> is -CO-NH-. The 90-1 Compound discloses no other alternative to this Z group. Accordingly, the 90-1 Compound does not disclose all of the limitations of the instantly claimed compound, and therefore cannot anticipate the instant claims.

**(3) Japanese Patent No. 59-36674**

On pages 7 and 8 of the Office Action, the Examiner rejects claims 1, 2, 4, 5, 8, 9, and 13 under 35 U.S.C. § 102(b) as allegedly being anticipated by Japanese Patent No. 59-36674 (the “‘674 Patent”). In view of amended claim 1, Applicant respectfully submits the rejection is overcome. In particular, amended claim 1 relates to a compound of formula (I) where R<sup>4</sup> or R<sup>5</sup> can indeed be a hetaryl, but if they are, they cannot be pyridyl or furyl. Furthermore, while R<sup>4</sup> or R<sup>5</sup> can be an unsaturated heterocycle, this is only possible for a bicyclic heterocycle; a monocyclic heterocycle must be saturated. Thus, under no circumstances can R<sup>4</sup> or R<sup>5</sup> be pyridyl or furyl. In contrast, the compounds disclosed by the ‘674 Patent have, at the equivalent to one of R<sup>4</sup> or R<sup>5</sup> of instant formula (I), only pyridyl or furyl. The ‘674 Patent does not teach any other alternative at the equivalent of R<sup>4</sup> or R<sup>5</sup>. Accordingly, the ‘674 Patent does not disclose all of the limitations of the instantly claimed

compound, and therefore cannot anticipate the instant claims. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 102 over the 24-1 Compound, the 90-1 Compound, and the '674 Patent.

**c. 35 U.S.C. § 103**

On pages 8 and 9 of the Office Action, the Examiner rejects claims 1, 2, 4, 5, 8, 9, and 13 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '674 Patent. The Examiner asserts that the compounds disclosed by the '674 Patent differ from those of the instant claims only in that a hydrogen atom in the anti-secretory compounds of the '674 Patent has been substituted for a methyl group on the phenyl ring that corresponds to W1 of instant formula (I), or a methoxy group has been substituted for an ethoxy group corresponding to group A of instant formula (I). The Examiner concludes that it would have been obvious for one of ordinary skill in the art to modify the compounds of the '674 Patent to arrive at the instantly claimed compounds. In view of the amended claims, Applicant respectfully disagrees.

The instantly claimed compounds do not simply differ from the '674 Patent between by an alkyl instead of a hydrogen at phenyl group W1, or by an methoxy instead of ethoxy at group A. Instead, the '674 Patent compounds can only have a pyridyl or furyl group at the equivalent to R<sup>4</sup> or R<sup>5</sup> of instant formula (I), while the instantly claimed compound cannot have either of these groups at R<sup>4</sup> or R<sup>5</sup>. And the '674 Patent discloses that only the pyridyl- and furyl-containing compounds that it discloses have anti-secretory activity. No alternative is taught. Accordingly, the '674 Patent does not provide any evidence that another type of group can be substituted for the R<sup>4</sup> or R<sup>5</sup> pyridyl or furyl, yet still maintain the purported anti-secretory activity of the compound.

In stark contrast, the instant specification discloses at Examples 1-226 and Table 1 that the instantly claimed compounds, which have heteroaryl groups at R<sup>4</sup> or R<sup>5</sup> that do not overlap with compounds of the '674 Patent, and are capable of modulating 5-HT<sub>5A</sub> activity with some of the compounds at a K<sub>i</sub> of less than 50 nM. Since the '674 Patent does not disclose any link between the compounds it teaches and anti-secretory activity of the compounds, one of skill would a priori have expected that any change to the R<sup>4</sup> or R<sup>5</sup> pyridyl or furyl groups would abolish anti-secretory activity of the compounds. Accordingly, one of ordinary skill in the art would not have had a reasonable expectation of success in modifying the compounds of the '674 Patent while avoiding any abrogation of anti-secretory activity, let alone achieving 5-HT<sub>5A</sub> modulatory activity, about which the '674 Patent discloses absolutely nothing. Because of ordinary skill in the art would not have had a reasonable expectation of success in modifying the compounds of the '674 Patent to arrive at the

instantly claimed compounds, the instant claims are not obvious over the '674 Patent. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 103.

### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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